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EXAMINER

LEUNG, JENNIFER A

ART UNIT

PAPER NUMBER

1764

DATE MAILED: 04/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/578,224	Applicant(s) SCHWALBE ET AL.	
	Examiner Jennifer A. Leung	Art Unit 1764	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-71 is/are pending in the application.
- 4a) Of the above claim(s) 27-70 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 and 71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-71 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 May 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2,4,6,8,10</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, Invention IA (claims 1-26 and 71) in Paper No. 9 is acknowledged. The traversal is on the ground(s) that since, "the classification of [Inventions IA, IB, and IC] is the same, it is clear that examining the three inventions together would not represent an additional or serious burden on the Examiner." (page 1, lines 22-28; page 2, lines 23-30).

This is not found persuasive because although the Examiner has previously classified each of Inventions IA, IB and IC in class 422, subclass 188, such classification was provided to designate only the *general* subject matter of the instant inventions (i.e. the class/subclass area of "chemical apparatus including plural reaction stages"). To further clarify the search areas required for the specific components as claimed in Inventions IA, IB and IC, respectively, the following classifications are provided:

With respect to Invention IA, claim 1 recites a modular system comprising a control module, a reactant supply source, and a first reaction module, classified in class 422, subclasses 105 and 129. With respect to Invention IB, claim 27 recites a modular system comprising a control module, a pump module, and a reaction module comprising heat transfer means, classified in class 422, subclass 198. With respect to Invention IC, claim 30 recites a modular system comprising a pump module and a reaction module, classified in class 422, subclass 188.

For the reasons set forth in the prior Office Action in addition to the reasons set forth above, the requirement is still deemed proper and is therefore made **FINAL**.

2. Claims 27-70 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as

being drawn to a nonelected invention, there being no allowable generic or linking claim.

3. The Examiner apologizes for any inconvenience caused by the absence of a clear indication of the separate future classification and field of search required of the inventions in the Restriction requirement of the prior Office Action.

Drawings and Specification

4. FIG. 14 is objected to as failing to comply with 37 CFR 1.84(p)(5) because it lacks reference sign "92a" mentioned in the description on page 22, lines 18, 19 and 22. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

5. The drawings and specification have not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-26 and 71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 1, the phrase, "a desired chemical product" (lines 1, 4 and 13) is considered vague and indefinite, as it is unclear as to what product applicants consider desirable. Likewise in the subsequent claims, i.e. claim 5 (line 2), claim 10 (lines 6, 7), claim 10 (line 2), claim 13 (line 2), claim 16 (line 3), claim 25 (lines 1, 8), and claim 71 (lines 1, 4, 12).

With respect to claim 3, the language of the claim is directed to a method limitation which renders the claim vague and indefinite as it is unclear as to what structural elements the applicants are attempting to recite, since “at least one of said plurality of reactants” is not considered an element of the apparatus.

With respect to claim 9, “said additional reaction module” (lines 4 and 9-10) lacks proper positive antecedent basis. See also comments for claim 10.

With respect to claim 10, the phrase “sufficient additional reaction modules” (lines 1-2) is considered vague and indefinite, as it is unclear as to what applicants consider sufficient. Furthermore, it is unclear as to the relationship of “an additional reaction module” (line 4) to the “additional reaction modules” set forth in line 2. Furthermore, it is unclear as to the structural relationship of the “additional reaction modules” to the other elements of the apparatus.

With respect to claim 11, it is unclear as to the structural limitation applicants are attempting to recite by, “configured to enable it to produce a class of chemical products” (line 2) and likewise by, “configured to facilitate the production of a different class of chemical products” (lines 4-5).

With respect to claim 14, it is unclear as to the structural relationship of “a heat exchanger”, “a temperature sensor” and “a reactant laminar flow mixing passage” to the other elements of the apparatus.

With respect to claim 23, the phrase, “undesired material” (line 2) is considered vague and indefinite, as it is unclear as to what material applicants consider undesirable.

With respect to claim 25, the language of the claim is directed to a method limitation which renders the claim vague and indefinite as it is unclear as to what structural elements the

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applicants are attempting to recite, since “a quantity of said desired chemical product produced by the module system” (lines 1-2) is not considered an element of the apparatus, and furthermore, lines 4-10 are drawn to process steps (i.e. the steps of “replacing said pump module...”, “replacing said replaceable reactor...”, and “replacing said first reaction module...”), which provide no structural limitation in apparatus claims. Furthermore, it is unclear as to the structural limitation applicants are attempting to recite by, “configured to provide an increased rate of production of the desired chemical product” (lines 7-8).

With respect to claim 26, the terms “quick” and “rapid” are considered vague and indefinite, as they are relative terms.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 3-5, 9, 10, 13, 14, 18, 20, 22, 25 and 71 are rejected under 35 U.S.C. 102(b) as being anticipated by Chaussonnet (U.S. 5,730,947).

With respect to claims 1 and 71, Chaussonnet discloses an apparatus comprising:

- (a) a control module, being adapted to monitor and control production of a chemical product in the apparatus (i.e. inherent of the apparatus, in order to enable the disclosed regulation of temperature, pressure, and flow rate; column 3, lines 54-59; column 5, lines 63-67);
- (b) a reactant supply source for a plurality of reactants (i.e. storage tanks **17, 19**), a flow of each reactant from its reactant supply source being controlled by the control module (i.e. via regulation of metering pump **18**; FIG. 1; column 3, lines 23-59);

(c) a first reaction module (i.e. thermolysis chamber **4** defined by thermolysis enclosure **4A**) in fluid communication with each reactant supply source **17, 19** to receive the plurality of reactants, being controllably connected to the control module and including a replaceable reactor (i.e. the thermoreactor, comprising components **5, 6** and **7**, being “removably housed”; FIG. 2; column 5, lines 13-32) which automatically produces the chemical product from the plurality of reactants under the control of the control module.

With respect to claim 3, no further structural limitations are recited and therefore the apparatus of Chaussonnet meets the claims, since “at least one of said plurality of reactants” is not considered an element of the apparatus. In any event, Chaussonnet further disclose at least one of said plurality of reactants is in a gaseous state (i.e. the combustible gas mixture of storage tank **19**; column 3, lines 23-27, 34-39).

With respect to claim 4, Chaussonnet further disclose a pump module (i.e. metering pump **18**) controllable connected to the control module, the pump module **18** being in fluid communication with each reactant supply source **17, 19** and with said first reaction module **4, 4A**, the pump module **18** capable of pumping at least one fluid through the apparatus (FIG. 1, 2; column 3, lines 23-59).

With respect to claim 5, Chaussonnet further discloses an additional processing module (i.e. purification chamber **9**) in fluid communication with the first reaction module **4, 4A** (FIG. 1, 2; column 3, line 66 to column 4, line 7).

With respect to claim 9, Chaussonnet further discloses that the additional processing module **9** comprises a second reaction module **10** in fluid communication with the first reaction module **4, 4A**, such that a serial fluid path is created with respect to the first reaction module **4,**

4A, the additional reaction module **10** being controllably connected to the control module (i.e. via gas analyzer **30**, pressure sensor **16**) and including a replaceable reactor (i.e. “they [cartridges **10**] are removable”) that produces the chemical product from a reaction of the plurality of reactants, so that the apparatus produces the chemical product using a plurality of reaction steps, a first step being completed in said first reaction module **4**, **4A** (i.e. via thermolysis), and a second step being completed in said additional reaction module **10** (i.e. via chemical purification), (FIG. 2; column 6, lines 1-19).

With respect to claim 10, Chaussonnet further discloses the provision of additional reaction modules **10** so that production of the chemical product can be achieved using additional steps (i.e. “the successive cartridges **10** can be of different kinds to fix different chemical radicals”; column 6, lines 8-19), each additional step being completed in an additional reaction module **10**.

With respect to claims 13-14, Chaussonnet (column 5, lines 13-32; FIG. 2) further discloses the first reaction module **4**, **4A** comprises means for facilitating production of the desired chemical product, wherein said means may comprise a heat exchanger (i.e. radiant electric tubes **6**) and a temperature sensor (i.e. thermocouple **15**).

With respect to claim 18, Chaussonnet (FIG. 1; column 3, lines 23-59) further discloses the pump module comprises at least one pump **18**, the at least one pump being inherently, controllably, connected to the control module (i.e. to enable the disclosed regulation of the flow rate of the metering pump **18**).

With respect to claim 20, Chaussonnet (FIG. 1; column 3, lines 23-59) further discloses the at least one pump **18** is in fluid communication with both the reactant supply source **17**, **19**

for at least one of the plurality of reactants, and the first reaction module **4, 4A**.

With respect to claim 22, the pump module **18** of Chaussonnet inherently comprises at least one valve (i.e. since it is by definition a “metering” pump; FIG. 1; column 3, lines 56-59), being controllably connected to the control module to control the flow reactants to the first reaction module **4, 4A**.

With respect to claim 25, no further structural limitations are recited and therefore the apparatus of Chaussonnet meets the claim. In any event, Chaussonnet (column 2, line 63 to column 3, line 6) further discloses the quantity of chemical product produced is increasable by replacing the replaceable reactor (i.e. the thermoreactor, comprising components **5, 6, 7**) in the first reaction module **4, 4A** with a different replaceable reactor configured to provide an increased rate of production of the chemical product (i.e. a different thermoreactor by “modifying the cross section of the reactor”), or by replacing the first reaction module **4, 4A** with a different reaction module configured to provide an increased rate of production (i.e. a different module by “modifying the length of the thermolysis chamber”).

Instant claims 1, 3-5, 9, 10, 13, 14, 18, 20, 22, 25 and 71 structurally read on the apparatus of Chaussonnet.

8. Claims 1, 3-5, 9-11, 13-15, 18, 20-23, 25-26 and 71 are rejected under 35 U.S.C. 102(b) as being anticipated by Bard (U.S. 5,580,523).

With respect to claims 1 and 71, Bard (FIG. 2, 3, 4; generally, column 4, lines 21 - column 5, line 18 and column 6, line 66 - column 7, line 20) discloses a modular system comprising:

(a) a control module, being adapted to monitor and control production of a chemical product

in the modular system (i.e. a computer interface for communicating with a master control center, such as a computer, wherein the interface is designated as reference **90**, unlabeled in FIG. 4);

(b) a reactant supply source **A**, **B** for a plurality of reactants, a flow of each reactant from its reactant supply source being controlled by the control module;

(c) a first reaction module in fluid communication with at least one reactant supply source **A**, **B** to receive at least one of the plurality of reactants, the first reaction module being controllably connected to the control module and including a replaceable reactor **R** (i.e. configured as a detachable and interchangeable reaction chip type unit, thereby “replaceable”; column 2, lines 32-47; column 4, lines 53-64), wherein the replaceable reactor **R** automatically produces the chemical product from the plurality of reactants **A**, **B** under the control of the control module.

With respect to claim 3, no further structural limitations are recited and therefore the apparatus of Bard meets the claims, since the “at least one of said plurality of reactants” is not considered an element of the apparatus. The selection of a “gaseous state” for one of said plurality of reactants is merely a recited intended use, which holds no patentable weight in apparatus claims.

With respect to claim 4, Bard further discloses a pump module (i.e. comprising pump **P_A** and **P_B**) controllably connected to the control module (i.e. via signal **P**), the pump module being in fluid communication with each reactant supply source **A** or **B** and with said first reaction module, the pump module pumping at least one fluid **A**, **B** through the modular system (FIG. 4; column 7, lines 9-20).

With respect to claims 5 and 9-10, Bard further discloses an additional processing module may be placed in fluid communication with the first reaction module, wherein the additional

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processing module may comprise a second reaction module in fluid communication with the first reaction module in a serial fluid path configuration, wherein the additional reaction module is controllably connected to the control module and includes a replaceable reactor (i.e. a reactor **R**), so that the modular system produces the chemical product using a plurality of synthesis steps, a first synthesis step being completed in the first reaction module and a second synthesis step being completed in the second reaction module, or additional steps being performed each in a desired number of additional reaction modules. (i.e. which reads on Bard's disclosure of a "serial placement of reactors to allow controlled sequential reactions of intermediates"; the provision of "a plurality of individual, detachable reaction units", wherein "one of the reaction units may be structurally different and capable of permitting a different chemical process of being performed"; column 2, lines 32-47 and 61-67; column 4, lines 53-58).

With respect to claim 11, Bard further discloses the replaceable reactor **R** may be configured to enable it to produce a class of chemical products (i.e. classes of chemical products synthesized by either "thermal, electrochemical, catalytic, enzymatic, photochemical, or hollow chamber type" reactors; column 2, lines 32-47; column 4, lines 53-64), and is selectively readily removable from the first reaction module and replaceable with a different replaceable reactor **R** configured to facilitate the production of a different class of chemical products.

With respect to claims 13-14, Bard (column 7, lines 1-20) further discloses the first reaction module comprises means for facilitating production of the desired chemical product, wherein said means comprises a heat exchanger (i.e. the "heat transfer system" illustrated as **H** in FIG. 4, not labeled in the specification) and a temperature sensor (i.e. thermocouple **TC**).

With respect to claim 15, Bard further discloses the control module may operate by

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transmitting signals generated from the detectors **D₁**, **D₂**, thermocouple **TC**, and flowmeter **FM** to a computer through an interface **90** to control the flow of reagents **A**, **B** and the temperature of the reaction (FIG. 4; column 7, lines 1-20). Although Bard does not specifically disclose that the computer comprises “a memory” for storing machine instructions and “a processor” to effect automatic control of the modular system, the Examiner takes Official Notice that it is well known in the art that a memory and a processor are inherent components of a computer.

With respect to claim 18, Bard further discloses the pump module comprises at least one pump (i.e. pumps **P_A** and **P_B**), the at least one pump being controllably connected to the control module to control its operation (FIG. 4; column 4, lines 35-37; column 7, lines 9-20).

With respect to claims 20-21, Bard further discloses at least one pump **P_A**, **P_B** in fluid communication with both the reactant supply source for at least one of the plurality of reactants and the first reaction module, wherein a separate pump is provided for each of the plurality of reactants **A**, **B** for communication with the first reaction module (i.e. pump **P_A** provided in communication with reactant supply source **A**; pump **P_B** provided in communication with reactant supply source **B**; FIG. 4).

With respect to claim 22, Bard further discloses the pump module comprises at least one valve (i.e. comprising valves **V_A**, **V_B**), being controllably connected to the control module (i.e. valve signal **V**) to control a flow of one of the plurality of reactants **A**, **B** to the first reaction module (FIG. 4; column 7, lines 9-20).

With respect to claim 23, Bard further discloses that the modular system may comprise separatory components for performing a desired chemical process, and further illustrates the desired chemical process of penicillin fermentation, wherein the pump module comprises filter

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banks **502**, **503**, for filtering undesired material from Benzylpenicillin (BP) before the BP flow to the reaction module (FIG. 8; column 4, lines 21-29, 46-52; column 6, lines 34-40; column 8, lines 35-67).

With respect to claim 25, no further structural limitations are recited, and therefore the apparatus of Bard meets the claim, since the process of increasing chemical product is not considered an element of the apparatus. In any event, Bard discloses the quantity of chemical product produced may be increased by replacing the replaceable reactor in the first reaction module with a different replaceable reactor configured to provide an increased rate of production of the chemical product (i.e. which reads on providing a reaction chamber of a desired volume, column 5, lines 28-31).

With respect to claim 26, Bard (FIG. 2, 3; column 4, lines 30-36; column 6, lines 26-33) further discloses the modules may be fastened together for easy replacement and/or interchangeability using quick connect connectors (i.e. pins **30-37** or clips).

Instant claims 1, 3-5, 9-11, 13-15, 18, 20-23, 25-26 and 71 structurally read on the apparatus of Bard.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bard (U.S. 5,580,523) in view of Dugan (U.S. 5,658,537).

With respect to claim 2, (FIG. 4; column 7, lines 1-20) replaceable reactor **R** inherently defines a reaction volume. Also, Bard discloses a chip type mixer **Mx**, which inherently defines a mixing volume, upstream of the replaceable reactor **R**. However, Bard is silent as to whether the replaceable reactor **R** volume and the chip type mixer **Mx** volume may be configured integrally such that the replaceable reactor **R** comprises both the mixing volume and the reaction volume. In any event, it would have been an obvious design choice for one of ordinary skill in the art at the time the invention was made to configure the replaceable reactor **R** in the apparatus of Bard to comprise both a mixing volume and a reaction volume, on the basis of suitability for the intended use and absent showing any unexpected results thereof, since it has been held that making elements integral involves ordinary skill in the art. *Nerwin v. Erlichman* 168 USPQ 177 (PO BdPatApp 1969); *In re Wolfe* 116 USPQ 443 (CCPQ 1958); *In re Howard* 150 US 164 (USSC 1893). Furthermore, such a configuration is known in the art, as evidenced by Dugan. In particular, Dugan teaches a plate-type chemical reactor, which comprises both a reaction volume and a mixing volume defined by a static mixing means incorporated into the reactor (Abstract;

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column 2, lines 16-68; column 3, lines 1-13). The integration of the mixing means with the reactor allows improved temperature control over the mixing process, as taught by Dugan.

10. Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bard (U.S. 5,580,523) in view of Ghosh et al. (U.S. 5,961,932).

With respect to claims 6-7, Bard discloses the modules may comprise a reaction chamber having an I.D. of up to 100 μm to optimize the control of *residence time* within a reaction zone, thereby comprising a “residence time module” by definition (Abstract; column 3, lines 31-36); wherein the chamber may be formed by etching a preformed pattern of a desired volume onto a substrate (column 5, lines 28-31; generally in lines 1-18), the pattern inherently comprising a “capillary” by definition, as characterized by it having a very small internal diameter. However, Bard is silent as to whether the volume of the preformed pattern may be varied by selecting a capillary of a given length to obtain a predetermined amount of time (i.e. the “optimized” residence time) for the chemical product in the residence time module. Ghosh et al. teach a chemical reactor comprising a reaction chamber **34** which can be made longer by configuring serpentine, complex, wavy, winding and angular forms (i.e. “capillaries”, as characterized by the forms of very small internal diameter) to allow for longer reaction time (column 5, lines 15-19). It would have been an obvious design choice for one of ordinary skill in the art at the time the invention was made to modify the residence time module of Bard such that it comprised a capillary of an appropriate length selected to obtain a predetermined residence time for the reaction, on the basis of suitability for the intended use and absent showing unexpected results thereof, since such would allow for the reaction chamber to be designed specifically for a given reaction or reagent/product. Furthermore, it has been held that changes in size involve only

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ordinary skill in the art. *In re Rose*, 220 F.2d 459, 463, 105 USPQ 237, 240 (CCPA 1955), and where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art, *In re Aller*, 105 USPQ 233.

With respect to claim 8, Bard discloses that the “system provides for uniform temperature control for continuous flow reactors under *elevated pressures*. This allows for precise control of *residence time* within a reaction zone.” (column 2, lines 48-51). Bard further discloses, “flow control components that make-up the ICS system can include pumps, flow channels, manifolds, flow restrictor, *valves*, etc.” (column 4, lines 36-37). Therefore, the provision of a proportional valve for the residence time module, controllably connected to the control module to selectively vary a pressure within the modular system, would be inherent of the apparatus of Bard, in order to enable the regulation of the recited elevated pressures (see also, column 3, lines 54-59).

11. Claims 12 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bard (U.S. 5,580,523).

With respect to claim 12, Bard discloses that a key aspect of the invention is to “provide an Integrated Chemical Synthesizer (ICS) system that is modular in design...” wherein “[t]he modular nature of the system, component parts, e.g. the reactors, flow channels..., allows easy replacement and/or interchangeability of the component parts.” (column 2, lines 32-47). Bard discloses that to provide such ease, the component parts may comprise a housing (i.e. illustrated as a chip unit **100**; FIG. 1d, 2, 3), wherein the housing **100** comprises a first side having a port **10** and a second side having a port **11**, enabling communication with the reactant supply and additional processing modules. Bard also discloses that housing **100**, which defines the replaceable reactor **R**, is removably connected to the other system components via mounting and

dismounting housing **100** from mounting frame or assembly board **20** (column 6, lines 26-33).

Although Bard is silent as to the provision of a product reservoir, it would have been an obvious design choice for one of ordinary skill in the art at the time the invention was made to provide a product reservoir to the apparatus of Bard, on the basis of suitability for the intended use and absent showing any unexpected results thereof, since the Examiner takes Official Notice that it is conventionally known in the art to provide a product reservoir to a chemical reactor, in order to enable the recovery of product from the apparatus (i.e. to enable recovery of product in streams **214, 309, 410, 509, 607** or **609**, illustrated Examples 1-4; FIG. 5-9). Furthermore, regarding the provision of a plurality of ports, it would have been an obvious design choice for one of ordinary skill in the art at the time the invention was made to provide a plurality of ports for the port of the apparatus of Bard, on the basis of suitability for the intended use (i.e. for enabling feed of plural reactants **A, B** individually) and absent showing any unexpected results thereof, since duplication of part was held to have been obvious. *St. Regis Paper Co. v. Beemis Co. Inc.* 193 USPQ 8, 11 (1977); *In re Harza* 124 USPQ 378 (CCPA 1960).

With respect to claim 24, Bard further discloses that, “flow control components that make-up the ICS system can include pumps...” and “[t]hese components will have the necessary fittings that allow them to be sealed with the pre-arranged or selectively located flow channels or connectors.” (column 4, lines 35-41). However, Bard is silent as to whether the pump module (i.e. comprising pumps **P_A** and **P_B**) may comprise a housing, wherein the housing comprises a plurality of ports on a first and a second side to enable the pump module to be controllably connected to the control module and to be in fluid communication with the reactant supply source **A, B** and the first reaction module. In any event, it would have been an obvious design

choice for one of ordinary skill in the art at the time the invention was made to provide such for the pump module in the apparatus of Bard, on the basis of suitability for the intended use and absent showing any unexpected results thereof, because provision of a housing and a plurality of ports for the pump module would enable easy replacement and/or interchangeability of component parts as a single unit (i.e. for ease in sealing the components with the pre-arranged or selectively located flow channels or connectors), as evidenced by the provision of a housing and a plurality of ports to the reaction module of Bard, as discussed in claim 23 above.

12. Claims 16-17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bard (U.S. 5,580,523) in view of Ashmead et al. (U.S. 5,534,328).

With respect to claim 16-17 and 19, Bard (FIG. 1d, 3) further discloses a plurality of fluid paths (i.e. channels **10**, **11**, **81**, **82**, **83**, **84**), including a fluid path for each of the plurality of reactants (i.e. reactants **A**, **B**, flowing into channels **81**, **10**; also illustrated in FIG. 4), and a fluid path for the product (i.e. intermediate products flowing through channels **11** and **82** or **83**; final product flowing out of the modular system, via channels **11**, **84**). Bard further discloses a heat transfer system (i.e. illustrated as **H** in FIG. 4; column 7, lines 1-20). However, Bard is silent as to whether the heat transfer system may comprise at least one fluid path for a heat transfer media and at least one fluid path for a spent heat transfer media, wherein the fluid paths are configured in one of a parallel fluidic system and a serial fluidic system, and wherein at least one pump is provided in fluid communication with both a heat transfer media fluid supply and the first reaction module. In any event, it would have been an obvious design choice for one of ordinary skill in the art at the time the invention was made to select such a configuration for the heat transfer system of Bard, on the basis of suitability for the intended use and absent showing any

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unexpected results thereof, since substitution of known equivalent structures involves only ordinary skill in the art. *In re Fout* 213 USPQ 532 (CCPA 1982); *In re Susi* 169 USPQ 423 (CCPA 1971); *In re Siebentritt* 152 USPQ 618 (CCPA 1967); *In re Ruff* 118 USPQ 343 (CCPA 1958). Furthermore, such heat transfer systems (i.e. systems comprising flowing, fluid heat transfer media) are conventionally known in the art, as evidenced by Ashmead et al. In particular, Ashmead et al. (FIG. 3, 10; column 2, lines 4-17; column 11, line 66 to column 12, line 15) teach a reaction module comprising a heat exchanger 74, wherein the heat exchanger comprises at least one fluid path for a heat transfer media (i.e. via inlet port 75 and flow channels 74C) and at least one fluid path for a spent heat transfer media (i.e. via channels 74C and outlet port 76), wherein the fluid paths are configured in a parallel fluidic system (i.e. parallel pathways for channels 74C, divided by 77-1, 77-2). Ashmead et al. further teach that external flow control means (not shown) may be used for controlling the temperature of the heat exchanger 74, wherein such external flow control means may comprise a heat transfer media fluid supply (i.e. "a water bath") and known control devices, such as "pumps" (column 7, lines 28-47).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer A. Leung whose telephone number is 703-305-4951. The examiner can normally be reached on 8:30 am - 5:30 pm M-F, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Glenn A. Caldarola can be reached on 703-308-6824. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Jennifer A. Leung

April 11, 2003 JAL

Hien Tran

**HIEN TRAN
PRIMARY EXAMINER**